Who May Participate on the Clinical Research Team: Required Credentialing

Purpose

This policy summarizes the required credentialing of individuals who conduct human subjects research under the jurisdiction of Boston Children's Hospital (BCH).

Policy

Boston Children's Hospital (BCH) is committed to assuring that all individuals who perform research under its jurisdiction are appropriately qualified to perform the roles assigned.

BCH also recognizes that collaborative efforts exist among institutions and that from time-to-time individuals who are not part of the BCH workforce may be asked to assist in conducting a research protocol under the jurisdiction of the BCH IRB.

A reliance agreement may eliminate the need for duplicate IRB reviews at multiple institutions, but it does not eliminate the need for credentialing of individuals who intervene with or interact with research subjects at BCH. In all instances there must be appropriate credentialing and oversight for all members of the research team as a method of minimizing risks to research subjects.

Research teams consist of different roles and the nature of the research activity will determine the extent of the required credentialing process. Those involved with recruiting or obtaining consent from research subjects or conducting research assessments will have more requirements. Individuals who have limited roles such as data abstraction, coding or analysis with identified information will have fewer requirements.

It is important to note that individuals who do not interact with subjects and do not access private identifiable data (such as those who perform data analysis with de-identified data or serve as general consultants) are not considered engaged in human subject research and these guidelines do not apply to them.

Procedure

The following guidelines are meant to enable multi-institutional research activities while still adhering to required institutional oversight and credentialing priorities. They will be applicable to many situations, however, it is important to note that each case may need to be reviewed on an individual basis and the IRB has the ability to limit certain activities to BCH workforce members as part of its regulatory responsibility to assure that risk to research subjects is minimized.

While these are general guidelines to be followed, situations may be individually reviewed by the IRB office and with the Office of General Counsel and BCH Compliance Office as deemed necessary.

Credentialing of individuals who participate in human subject research

A. BCH workforce members who may serve as Principal Investigators (PI):

Please see the IRB policies: ***Who May Serve as Principal Investigator*** and ***Principal Investigator Responsibilities*** which sets forth the requirements and responsibilities for serving as a PI at BCH.

B. BCH workforce members who may serve as a research team member

Research Team Members perform the research under the direction and supervision of the Principal Investigator:

- All those who may serve as PI may also serve as research team members.
- Nurses who do not meet the criteria to serve as PI and who are credentialed through the BCH nursing department. This may include visiting nurses, faculty and students from institutions who are here under formal agreements.
- Research Coordinators employed by BCH or the associated foundations.
- BCH employees from other departments or foundations (i.e. social work, pharmacy, physical therapy).
- Medical students, residents, and fellows while rotating or training at BCH are eligible. It is also recognized that some institutions have joint training programs that permit activities at multiple locations; these joint trainees may serve on the research team.
- BCH volunteers who have been registered through the BCH volunteer office, receive the appropriate training, and are approved by the PI.
- BCH Associated Personnel who have been granted a badge and CHID number who have received appropriate training about BCH policies and procedures and who have been approved by the PI.

C. Unaffiliated individuals who may serve as research team members

Individuals who are not affiliated with BCH as set forth in the above categories may participate as a research team member. However, such individuals must become appropriately credentialed in order to participate in the research.

Situations that require access to hospital information, security systems, BCH facilities, and other situations determined by the IRB will require that the individual become “Associated Personnel”.

Each situation will be evaluated individually, but in general the steps required could include:

- Competency to perform the assigned role by having appropriate credentials and training.
- Having appropriate knowledge of human research protection regulations as they relate to the roles they will perform.
- Having provided documentation of human research protections training per the IRB policy.
- Having an adequate understanding of the specific details of the protocol to perform their tasks.
- Cooperating in any oversight activities, investigations, and/or inquiries regarding the research and the role they have served.

Credential and review process for unaffiliated research team members

A. Unaffiliated physicians

Intervene or Interact with Research Subjects: All physicians who will intervene or interact with BCH research subjects must receive an appointment through the medical staff privilege process. This requires contact with the appropriate Boston Children's Hospital Department Chair or Division Chief and the Medical Staff Registrar.

Activities limited to access of identified subject information: For activities that do not include direct interaction with research subjects, but include access to hospital information, security systems, facilities and other situations deemed necessary by the IRB, physicians may only need to become "Associated Personnel."

B. Unaffiliated nurses and other Patient Care Services (Social Work, Nutrition, Pharmacy, etc.)

Intervene or Interact with Research Subjects: All nurses or other members of Patient Care Services who will intervene or interact with BCH research subjects must be credentialed through the BCH Nursing Staff Development Office and complete and sign the commitment statement.

Activities limited to access of identified subject information: For activities that include access to hospital information, BCH security systems, facilities and other situations deemed necessary by the IRB, nurses and members of health care services need to become Associated Personnel only.

C. Other unaffiliated research team members

PIs are fully responsible for determining that individuals listed on their protocol meet the appropriate qualifications in order to serve the roles they are assigned. In addition, there is an institutional procedure that needs to be followed in order to permit this participation.

Intervene or Interact with Research Subjects

1. The PI must specify the role the individual will play and describe their training and credentials.
2. In most situations a reliance agreement will need to be signed with the individual's home institution. In limited and rare situations an unaffiliated agreement may be utilized if there is no home institution. For more information about reliance agreements, see the IRB policy: ***Reliance Agreements.***
3. If access to BCH security and information systems is required these individuals must become Associated Personnel with BCH.

Activities limited to access of identified subject information: For activities that include access to hospital information, security systems, facilities and other situations deemed necessary by the IRB, other research team members need to become associated personnel only.

Examples

1. A physician is visiting for a 3-month period and wants to conduct interviews with research subjects. Under this policy this activity would not be permitted unless the physician receives appropriate appointments and credentialing through the medical staff registrar. Physicians and practicing psychologists cannot intervene or interact with any research subject without such appointments.

2. A BCH investigator wants to have a medical student from a California University recruit patient for a research study. Families will be approached while they are waiting in the emergency room. The investigator also asks that the medical student obtain informed consent. In order to consider permitting this arrangement, the following steps need to be taken:
    a. A reliance agreement with the individual's home institution may be required.
    b. The medical student will likely need to become Associated Personnel.
    c. The BCH IRB will determine whether the medical student may obtain informed consent of behalf of the investigator. This decision may depend on the patient population as well as the complexity and risks of the research.

3. A BCH investigator is collaborating with an investigator from another Harvard-affiliated Hospital (Hospital H). All research related procedures and assessments will occur at Hospital H. It is requested that research coordinators from Hospital H come to BCH clinics and recruit BCH patients for the study. The BCH IRB has agreed to rely on the IRB review of Hospital H, however, in order to allow the coordinators to come on site at BCH and recruit research subjects, the following steps need to be taken:
    a. A reliance agreement is established between Hospital H and BCH.
    b. Since access to BCH information systems is required the coordinators must become Associated Personnel.
    c. The BCH IRB will determine whether these individuals may obtain informed consent on behalf of the investigator. This may depend on the patient population as well as the complexity and risks of the research.

Related Content

IRB Policies

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Document Attributes

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